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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,714	04/27/2007	Anders Carlsson	D7873.0003	5273
32173	7590	03/16/2010		
DICKSTEIN SHAPIRO LLP			EXAMINER	
1633 Broadway			MILLIGAN, ADAM C	
NEW YORK, NY 10019				
			ART UNIT	PAPER NUMBER
			1612	
			MAIL DATE	DELIVERY MODE
			03/16/2010 PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/597,714

Applicant(s)

CARLSSON ET AL.

Examiner

ADAM MILLIGAN

Art Unit

1612

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-12,14,15,17-19,21-25,27 and 28 is/are pending in the application.
- 4a) Of the above claim(s) 24,25,27 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-12,14,15,17-19,21-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicants arguments, filed 12/4/2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-7, 9-12, 14, 15, and 17-19 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Herslof (WO 03/068267 – see PTO-892 dated 4/22/09) in view of Tomaru et al. (Colonic Giant Migrating Contractions Induced by Glycerol Enema in Anesthetized Rats - Japan. J. Pharmacol. Vol. 63, Pages 525 -528, 1993) and Klaschik et al (Constipation, Modern laxative therapy Support Care Cancer Vol. 11, Pages 679–685, 2003).

Applicants assert that Klaschik discloses a rectally-administered tablet, while the amended claims are now drawn to an injectable formulation. Also, while Klaschik mentions enemas, it further teaches the administration of enemas is problematic because of leakage, and the instant invention does not suffer from this drawback. Lastly, Applicants argue that adjusting the amount of water for a use as described in Klaschik is not valid since Klaschik's use involves administering a tablet.

Examiner disagrees. In addition to tablets, Klaschik teaches that rectal laxatives may include enemas and clysmas (Klaschik at p.683, rectal laxatives). Clysmas contain a combination of secretagogue-acting agents or stool softeners for rectal application (id). Enemas are the application of larger amounts of fluid into the rectum (id). The effect of the enema depends upon the amount of fluid applied (id).

It would have been obvious to one of ordinary skill in the art to formulate the clysmas or enema and modify the amount of fluid present to obtain the desired constipation relief. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

It is noted that dissolving constipation is only an intended use of the claimed composition. Also, the addition of the phrase "of the composition as a whole", while providing clarification, does not change the interpretation of "a constipation-dissolving amount". A "constipation-dissolving amount" is interpreted as any amount given that any amount of the composition would be expected to provide some dissolving effect and the instant claims are directed to a composition & not a method of treating the constipation.

Claims 21-23 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Herslof (WO 03/068267 – see PTO-892 dated 4/22/09) in view of Klaschik (Constipation, Modern laxative therapy Support Care Cancer Vol. 11, Pages 679–685, 2003), and Stemmler (U.S. 4,828,839).

Applicants argue that Stemmler teaches dynamic viscosity, but only to make the comparison between various batches of tablets to see if they are consistent with one another. Also, Applicants point out that Herslof does not teach that the composition itself has any particular viscosity, but test the composition after first swelling the tablets in water and stirring. Thus, Applicants argue that the dynamic viscosity disclosed is not related to the other prior art.

Examiner disagrees. As discussed above, the combination of Herslof and Klaschik renders a clyisma, or small enema obvious. In formulating the clyisma composition, the constipation-dissolving ingredients, which in Stemmler are taught to be in the form of a tablet, would be mixed with water. Thus, the fact that Stemmler discloses that the dynamic viscosity is related to dissolved ingredients (tablet) in water is consistent with the reasoning of the above rejection, and thus renders the dynamic viscosities recited in claims 21-23 obvious.

Further, since the viscosity of water at 20°C is 1.0020 millipascal seconds¹ (1.002×10^{-3} Pa·S), the addition of water is reasonably expected to decrease the viscosity of the composition rendered obvious which is taught to have a dynamic viscosity of 0.3 Pa·S to about 1.4 Pa·S. Thus, where the amount of water is adjusted to optimize constipation dissolving, the dynamic viscosity will also vary. In other words, the dynamic viscosity may be adjusted by adjusting the amount of water present for optimal constipation dissolving properties. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable

¹ The Physics Hypertextbook-Viscosity, <http://physics.info/viscosity/> accessed 3/11/2010.

ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Conclusion

No claims allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ADAM MILLIGAN whose telephone number is (571)270-7674. The examiner can normally be reached on M-F 9:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fred Krass can be reached on (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612

/A. M./
Examiner, Art Unit 1612